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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,228 | 03/12/2002 | Joe Z. Tsien | PU-0082 | 5571 |

7590

01/10/2005

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| EXAMINER |
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KELLY, ROBERT M

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,228

Applicant(s)

TSIEN, JOE Z

Examiner

Robert M Kelly

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22, drawn to a method of improving learning or memory or treating a neurodegenerative disorder that affects learning or memory, comprising modifying NMDA receptors to increase their function by at least 15%.

Group II, claim(s) 23-27, drawn to a transgenic animal with improved memory and learning, the genetic alteration resulting an increase in NMDA function at least 15% over that of normal.

Group III, claim(s) 28, drawn to a method to identify compounds that enhance learning and memory comprising providing a DNA construct with the NR2B promoter linked to a reporter sequence.

Group IV, claim(s) 29-34, drawn to a method to identify compounds that enhance learning and memory by affecting NR2B expression or NMDA activity comprising providing a pair of cells, one of which expresses an exogenous nucleic acid encoding NR2B.

Group V, claim(s) 35-39, drawn to an *in vivo* assay for identifying compounds that enhance NMDA receptor function comprising treating one of two animals with a test compound.

Group VI, claim(s) 40-43, drawn to an *in vitro* assay for identifying compounds that enhance NMDA receptor function, comprising treating one of a pair of cells with a test compound and measuring changes in NMDA function.

Group VII, claim(s) 44, drawn to a method of identifying genes or gene products that affect NMDA mediated learning and memory comprising providing a transgenic animal expressing an NR2B transgene, and a second animal that is not transgenic, comparing gene profiles, and isolating differentially-expressed genes.

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Group VIII, claim(s) 45-49, drawn to a method of identifying genes and gene products that affect NMDA mediated learning comprising stimulating NMDA receptors in a sample of cells, and comparing to another, non-stimulated, sample.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature between Groups I and II is that increasing NMDA receptor function leads to increased learning and/or memory. Tang, et al. (1999) Nature, 401 : 63-69 describes a transgenic mouse for NR2B that has increased memory and learning (ABSTRACT). [Note: Applicant has supplied Tang in an IDS, hence, it is not supplied in a citation of references, but will be addressed substantively during the first action on the merits of this Application.] Hence, there exists no special technical feature contributed by the present invention over the prior art regarding Groups I and II. Moreover, the special technical feature shared between Groups any two groups is the expression of NR2B and relations of such to memory and learning, which is similarly taught by Tang (ABSTRACT). Furthermore, each of the groups contains different, non-coextensive considerations that would pose a serious burden on the examiner to search and examine any two groups together. To wit, for example, Group I requires a consideration of neurodegenerative disorders and how they affect learning and memory; Group II requires a consideration of the each animal type and how NMDA is related to their learning and memory; Group III requires a consideration of what structure is required of reporter genes and what promoter elements are required; Group IV requires a consideration of what exogenous nucleic acids may be used in what types of cells; Group V requires a consideration of what direct and indirect methods may be used to assay changes in each type of animal; Group VI requires a consideration of the types of cells that may be used; Group VII requires a consideration of the types of transgenic modifications that can be used; and Group VIII requires a consideration of how to stimulate NMDA receptors. Hence, not only is the special technical feature taught for any two groups, but each group requires its own non-coextensive considerations that would pose a serious burden on the Examiner to consider any two groups together. As set forth above, each group has a special technical feature not shared by the other groups, and therefore, Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

